[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Anti-CD56 as an antibody-drug conjugate ("ADC") or non-ADC to target glioblastoma either alone or in combination with other potential immuno-oncology drugs.

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Connectyx Technologies Holdings Group ("Connectyx") located in Boca Raton, FL.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Jasmine Yang, Ph.D., Senior Licensing and Patenting Manager at Telephone: (240)-276-5530 or at E-mail: jasmine.yang@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

- 1) U.S. Provisional Patent Application No. 62/119,707 filed July 31, 2015. HHS Ref No. E-221-2015-0-US-01
- 2) PCT Application No. PCT/US2016/044777 filed 07/29/2016. HHS Ref. No. E-221-2015-0-PCT-02
- 3) US Patent No. 10,548,987 issued February 02, 2020 (Patent Application No. 15/747,620 filed January 25, 2018). HHS Ref. No. E-221-2015-0-US-03.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: Anti-CD56 as an antibody-drug conjugate ("ADC") to target and treat glioblastoma either alone or in combination with other potential immuno-oncology drugs.

This technology discloses the composition of an ADC comprising a drug conjugated to CD56-specific monoclonal antibodies, m900 and m906, or an antigenbinding fragment, wherein the drug comprises a cytotoxic agent, including but not limited to PBD, and to methods of using the ADCs for treating neuroblastoma, small-cell lung cancer, multiple myeloma, acute myeloid leukemia, NK-T lymphoma, and neuroendocrine cancer. This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

August 20, 2020.

Dated Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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